PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
M915-PCT		
International application No. PCT/JP 03/13954	International filing date *(day/month/year)* 30.10.2003	Priority date *(day/month/year)* 30.10.2002

International Patent Classification (IPC) or national classification and IPC

Int.Cl⁷

A61K39/00, A61K35/12, A61K38/17, A61K48/00, A61P35/00

Applicant

CHUGAI SEIYAKU KABUSHIKI KAISHA

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☑ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☑ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.11.2003	24.09.2004

Name and mailing address of the IPEA/JP	Authorized officer	
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Form PCT/IPEA/409 (cover sheet) (July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP 03/13954

I. Basis of the report

1. With regard to the **elements** of the international application:*

☑ the international application as originally filed

☐ the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☐ the claims:
Nos. _____ , as originally filed
Nos. _____ , as amended (together with any statement) under Article 19
Nos. _____ , filed with the demand
Nos. _____ , filed with the letter of _____

☐ the drawings:
sheets/figs _____ , as originally filed
sheets/figs _____ , filed with the demand
sheets/figs _____ , filed with the letter of _____

☐ the sequence listing part of the description:
pages _____ , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☑ contained in the international application in written form.

☑ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☑ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:
☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

International application No.
PCT/JP 03/13954

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-12	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-12	NO
Industrial applicability (IA)	Claims	1-12	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

・D 1 : TREON, et al. Immunotherapeutic strategies for the treatment of plasma cel l malignancies. Seminars in Oncology, 2000, vol.27, no.5, p.598-613
see the whole document, especially
line 47, right column, page 601 to line12, left column, page 602 ;
lines 4-36, left column, page 604 ;
line 10-36, left column, page 605

・D 2 : WO 01/77362 A1 (CHUGAI SEIYAKU KK) 2001.10.18
see the whole document, especially
claims ;
lines 1-21, page 4 ;
line 11, page 27 to line 24, page 33 ;
line 8, page 43 to line 11, page 51 ;
Registry No. 165944-11-6,239789-24-3,368511-79-9,368511-80-2,368511-81-3
& AU 2001/46846 B

None of the subject matter of claims 1-12 involves an inventive step either over D1 or over D1 and D2.

D1 discloses immunotherapeutic strategies including the following methods (1) to (3) f or the treatment of plasma cell malignancies such as multiple myeloma (MM) :

(1) immunization with functional dendritic cells pulsed with a tumor antigen or DNA enco ding a target tumor antigen (see [page 604,left column,line 4-36]) ,
(2) immunization directly with an target tumor antigen e.g. MM-ideotypic protein (see [p age 604, left column, line 38 - page 605, left column,line 8]) ,
(3) immunization with DNA plasmids encoding a target tumor antigen (see [page 605, le ft column, line 10-36]) .

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: V.

D1 does not concretely describe HM1.24 for the use as a target antigen for the above disclosed treatment of MM, however, D1 implies that HM1.24 would be one of the typical candidates as a target for antibody-mediated therapy of MM (see [page 599, left column, line 3 or page 601, right column, line 47 - page 602, left column, line 12]). Therefore, taking into consideration the above-mentioned implication, a person skilled in the art would easily employ either HM1.24 as a target antigen or HM1.24-encoding gene (e.g. DNAs disclosed in D2) as a gene thereof.